Australian Government
Department of Health
Therapeutic Goods Administration

Application ID: DV-2021-CR-02097-1
TGA Reference: E21-225604

Novapharm Research (Australia) Pty Ltd
3-11 Primrose Avenue
ROSEBERY NSW 2018

Email: meng.heng@regionalhealth.com.au

Attention: Meng Heng

Notice under section 9D of the *Therapeutic Goods Act 1989* of decision to vary ARTG Listing for Other Therapeutic Goods

ARTG	GMDN code and term	Therapeutic Type
343050	9950 Disinfectant, hospital grade	Other Therapeutic Good - Listed disinfectant

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 9D of the *Therapeutic Goods Act 1989* (the Act), I have decided to vary the Australian Register of Therapeutic Goods (ARTG) under subsection 9D(3) of the Act following your request on the basis that the information provided for this variation does not indicate any reduction in the quality, safety or efficacy of the kind of therapeutic goods for the purposes for which these goods are intended to be used.

Therefore, I have accepted to include RapidClean ActivePaper to ARTG 343050 Listed Entry.

Date of amendment: 3 March 2021

Relevant Legislation:

- *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Details/C2020C00028); and Unincorporated Amendments: *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* (C2018A00007) (https://www.legislation.gov.au/Series/C2004A03952);
- Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019. (https://www.legislation.gov.au/Details/F2019L00482)

Sponsors' ongoing regulatory responsibilities
Australian sponsors of therapeutic goods have ongoing regulatory responsibilities for the goods they supply to the Australian market.

The continued listing of the goods of the kind in the ARTG is subject to payment of annual charges.

Ongoing monitoring of quality, safety and efficacy
Therapeutic goods on the ARTG are subject to ongoing monitoring of their quality, safety and efficacy. At any time, the ARTG entry may be selected for a review to verify compliance of the goods with the regulatory requirements.

Review of the decision under section 60 of the Act
Should you wish to seek a review of my decision to vary the ARTG entry, your rights of review are outlined in Attachment A to this letter.

Yours sincerely

Signed and authorised by
Jane Shum (signed electronically)
Delegate of the Secretary for the purposes of section 9D of the Act
Medical Devices Branch
3 March 2021

Attachment A

Request for reconsideration of an initial decision
This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision
A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled **"<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

Email: '**minister.hunt.DLO@health.gov.au**' and copied to '**decision.review@health.gov.au**'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 40
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.